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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,660	04/15/2005	Luis Molina	11299.105005	3876

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,660	MOLINA, LUIS	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in the application.

Election/Restrictions

Applicant's election with traverse of the species: duramycin (lanbiotic), saline solution (pharmaceutical carrier) and topical administration (mode of administration) in the reply filed on 8/27/07 is acknowledged. The traversal is on the ground(s) that the Examiner did not provide a reason that it would be an additional burden to the office to search for different lanbiotic species, different pharmaceutically acceptable carriers or modes of administration. Applicant also points out that, even though Examiner has stated that these are not "so linked as to form a single inventive concept" and that these are not "art recognized equivalents" (citing PCT Rule 13.2 and PCT Administrative Instructions, Annex B, part I(f)(i)(B)(2). However, the Applicant notes that the 'general inventive concept' is that which is claimed in the independent claim, i.e., a method of treating dry eye disease by administering a therapeutically effective amount of a lanbiotic in a pharmaceutically acceptable carrier. This is not found persuasive because the international search report (ISR) of PCT/US03/29853 does indicate three Y references with respect to all the claims, therefore, the invention is not linked by a special technical feature. In addition, with respect to the lanbiotics, the compounds are drawn to many materially different compounds drawn to different compositions, which require different searches. Additionally, the carriers and mode of administration have

materially different effects and do also require different searches and consideration. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate one species of the invention would not necessarily anticipate or even make obvious another species of the instant invention. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above species in one application. Because these species are distinct for the reasons given above and the search required for each species is not necessarily required for the other species, election of species for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 are presented for examination on the merits as they read upon the species: a method of treating dry eye disease comprising administering to a subject in need of such treatment a therapeutically effective amount of duramycin in a saline solution via topical administration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (US 5,811,446) in view of Blackburn et al. (US 4,980,163).

Thomas teaches a method of treating blepharitis (eyelid bacterial inflammation which reads upon "dry eye disease") [e.g., column 1, line 39; column 5, lines 1-27] comprising administering to a subject in need of such treatment a therapeutically effective amount of a broad range antibiotic (e.g., column 3, line 24) and a saline solution carrier (e.g., column 9, line 18) via topical administration (e.g., column 9, lines 50-53; column 10, lines 30-36). Thomas also teaches antibiotic compositions acting preferably against *Staphylococcus sp,* specially, e.g., *S. aureus* (column 5, lines 1-18). The limitation of claim 3: --wherein said administering involves topical administration—is taught, e.g., in column 10, lines 30-36. The limitation of claim 4: --wherein said topical administration is via a carrier vehicle selected from a group consisting of drops of liquid, liquid washes, gels, ointments, sprays and liposomes—e.g., column 9, lines 50-53; column 10, lines 17-29. The limitation of claim 5: --wherein said topical administration comprises infusion of said compound to said ocular surface via a device selected from a group consisting of a pump-catheter system, a continuous or selective release device and a contact lens—is taught, e.g., in column 9, lines 50-53. The limitation of claim 6: --wherein said administering is systemic administration of said compound—is taught, e.g., in column 10, lines 39-40. The limitation of claim 8: --administration of an oral form of said compound such that a therapeutically effective amount of said compound contacts lacrimal tissues of said subject via systemic absorption and circulation—is taught, e.g., column 10, lines 55-60. The limitation of

claim 9: --administration of an injectable form of said compound, such that a therapeutically effective amount of said compound contacts lacrimal tissues of said subject via systemic absorption and circulation-- is taught, e.g., in column 10, lines 37-40. The limitation of claim 11: --administration of an intra-operative instillation of a gel, cream, powder foam, crystals, liposomes, spray or liquid suspension form of said compound, such that a therapeutically effective amount of said compound contacts the lacrimal tissues of said subject via systemic absorption and circulation-- is taught, e.g., column 10, lines 17-29.

Thomas does not teach the broad range antibiotic duramycin.

Blackburn et al. teach broad range antibiotic compositions (e.g., abstract) comprising duramycin (e.g., claim 1 and 9) which target *S. aureus* (e.g., claim 19). The limitation of claim 2: --wherein the lantibiotic is duramycin-- is taught, e.g., in claim 9 of Blackburn et al. The limitation of claim 3: --wherein said administering involves topical administration—is taught, e.g., in column 3, lines 44-48. The limitation of claim 4: --wherein said topical administration is via a carrier vehicle selected from a group consisting of drops of liquid, liquid washes, gels, ointments, sprays and liposomes—is taught, e.g., in column 3, lines 44-47 and column 4, lines 10-15. The limitation of claim 6: --wherein said administering is systemic administration of said compound—is taught, e.g., in column 3, lines 44-48. The limitation of claim 8: --administration of an oral form of said compound such that a therapeutically effective amount of said compound contacts lacrimal tissues of said subject via systemic absorption and circulation—is taught, e.g., column 3, line 7. The limitation of claim 11: --administration of an intra-

operative instillation of a gel, cream, powder foam, crystals, liposomes, spray or liquid suspension form of said compound, such that a therapeutically effective amount of said compound contacts the lacrimal tissues of said subject via systemic absorption and circulation-- is taught, e.g., column 3, lines 44-48.

The limitation of claim 7: --wherein said systemic administration involves administration of a nebulized liquid to oral or nasopharyngeal airways of said subject— such that a therapeutically effective amount of said compound contacts lacrimal tissues of said subject via systemic absorption and circulation— and the limitation of claim 10: -- administration of a suppository form of said compound, such that a therapeutically effective amount of said compound contacts lacrimal tissues of said subject via systemic absorption and circulation—are not expressly taught by either reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Thomas by using a broad range antibiotic composition comprising duramycin as taught by Blackburn et al. The skilled artisan would have been motivated to do so because Thomas teaches using a broad range antibiotic (e.g., column 3, line 24) in the method of treating blepharitis (column 1, line 39; column 5, lines 1-27), and the duramycin antibiotic composition taught by Blackburn is a broad range antibiotic (e.g., claims 1 and 9). There would have been a reasonable expectation of success, given that both Thomas and Blackburn teach that the antibiotic compositions are preferably effective against Staphylococcus aureus (e.g., column 5, lines 1-18 of Thomas, claim 19 of Blackburn et al.) that can be topically administered (e.g., column 3, lines 44-48 of Blackburn et al. and column 10, lines 30-36 of Thomas).

The adjustment of particular conventional working conditions (e.g., using other forms of administration, such as nebulization or suppositories) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., suitable modes of administration), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.". *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve the highest yield of the highest purity product in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 11/123,436. The instantly claimed invention and the invention claimed in Application '436 are both drawn to a method of treating dry eye disease (claim 1 of Application '436 is drawn to treating allergies and oculosystemic diseases, which read upon dry eye disease) comprising duramycin. Further, the instantly claimed method encompasses and/or is encompassed by the claimed method of Application '436

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcela M Cordero Garcia
Patent Examiner
Art Unit 1654

MMCG 12/07

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654